MAY 13 2011

510(k) Summary for

Dimension® HB1C Kit

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K102510

1. **Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:**

Manufacturer: Siemens Healthcare Diagnostics Inc

Newark, Delaware 19714-6101

Contact Information: Siemens Healthcare Diagnostics Inc.
500 GBC Drive

P.O. Box 6101

Newark, Delaware 19714-6101

Attn: A. Kathleen Ennis

Tel: 302-631-9352

Fax: 302-631-6299

Preparation date: August 24, 2010

2. **Device Name:**

Dimension® HB1C Kit containing HB1C Flex® reagent cartridges and HB1C Calibrator

Classification: Class II

Product Code: LCP/KRZ

Panel: Hematology

3. **Identification of the Legally Marketed Device:**

BIO-RAD Variant® II Hemoglobin A_{1c} - K070452

4. **Device Descriptions:**

The Dimension® HB1C kit contains Flex® reagent cartridges and calibrator. Each cartridge contains reagents used to measure total hemoglobin and hemoglobin A1c. The reagents are liquid and ready to use on the instrument. The calibrator in the kit is a five level lyophilized product. Each level is hydrated with 2.0mL of reagent grade water. The lot matched reagents and calibrator product are for use on all models of the Dimension® clinical chemistry system.

5. **Device Intended Uses:**

The HB1C assay on the Dimension® clinical chemistry system is an *in vitro* diagnostic assay for the quantitative determination of hemoglobin A1c (HbA1c) in human anticoagulated whole blood. Measurements of hemoglobin A1c are effective in monitoring long-term glucose control in individuals with diabetes mellitus.

6. Summary of the devices technological characteristics

The Dimension ® HB1C kit has the same characteristics as the BIO-RAD Variant® II Hemoglobin A_{1c}. A comparison of features is provided.

Feature	Predicate Device: BIO-RAD Variant® II HbA_{1c} K070452	New Device: Dimension ® HB1C kit
Similarities		
Intended Use	Both kits are for *in vitro* diagnostic use for the quantitative determination of hemoglobin A1c in human whole blood.	
Sample Type	Both devices are for use with human anticoagulated whole blood treated with EDTA.	
Calibrator	Both devices are calibrated with whole blood hemolysate provided in lyophilized form .	
Certification	Both methods certified by the NGSP as traceable to the Diabetes Control and Complications Trial (DCCT).	
Traceability	Both methods are traceable to the IFCC reference method.	
Sample Preparation	Both methods sample directly and dilute on board.	
Packaging	Both kits contain the reagents and calibrator.	
Differences		
Instrument	BIO-RAD Variant® II HPLC	All models of the Dimension® clinical chemistry system
Reporting Units	Reports in %HbA1c.	Reports in both %HbA1c and mmol/mol.
Analytical Measuring Range	3.1 – 18.5 % HbA1c	3.6 – 16.0 % [17 – 151 mmol/mol]
Calibrator levels	Provides two calibrator levels plus a diluent for preparation of additional levels.	Includes five calibrator levels.
Technology	Uses ion-exchange high-performance liquid chromatography (HPLC).	Uses turbidometric inhibition immunoassay (TINIA) for the HbA1c measurement and both devices use a modification of the alkaline hematin reaction for the total hemoglobin portion of the assay.

7. Method Comparison

A split sample method comparison was conducted using the new device, Dimension ® HB1C kit vs. the predicate, BIO-RAD Variant® II Hemoglobin A_{1c}. One hundred and twenty- six (126) human whole blood samples preserved with EDTA ranging from 4.4 to 16.3% HbA1c [25 – 160 mmol/mol] were used. The data was analyzed using Deming regression analysis. The analysis is as follows:

	%HbA1c			mmol/mol		
	Coefficient	95% CI		Coefficient	95% CI	
Intercept	0.44	0.12	0.75	2.17	-0.35	4.70
Slope	0.90	0.85	0.94	0.90	0.85	0.95
n	124[1]			123[2]		

[1] Two samples, out of range by one or both of the methods, were not included in the analysis

[2] Three samples, out of range by one or both of the methods, were not included in the analysis

8. Conclusion

Based on a review of the devices technological features and the method comparison study, the new Dimension® HB1C kit is substantially equivalent to the legally marketed device, BIO-RAD Variant® II Hemoglobin A_{1c}.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

MAY 13 2011

Siemens Healthcare Diagnostics Inc.
c/o Ms. Anna Marie Ennis
500 GBC Drive
PO Box 6101
Newark, DE 19714

Re: k102510

Trade/Device Name: Dimension® HB1C kit (Model DF 105A), Dimension® HB1C Calibrator
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated Hemoglobin Assay
Regulatory Class: Class II
Product Code: LCP & JJX
Dated: April 5, 2011
Received: April 7, 2011

Dear Ms. Ennis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K102510

Device Name: Dimension(r)HB1C Kit

Indications for Use:

The HB1C assay on the Dimension® clinical chemistry system is an in vitro diagnostic assay for the quantitative determination of hemoglobin A1c (HbA1c) in human anticoagulated whole blood. Measurements of hemoglobin A1c are effective in monitoring long term glucose control in individuals with diabetes mellitus.

Prescription Use XX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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Indications for Use Form

510(k) Number (if known): K102510

Device Name: Dimension(r)HB1C Calibrator

Indications for Use:

The HB1C CAL is an in vitro diagnostic product for the calibration of the Hemoglobin A1c (HB1C) method on the Dimension® clinical chemistry system.

Prescription Use XX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
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